

## **REMARKS**

Applicants have amended claims 1, 5 and 23 to correct formal matters and to clarify the subject matter to be claimed. Applicants have added claim 28. Support for the amended and added claims appears throughout the specification and claims as originally filed.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### **I. Status of the Claims**

The Examiner states that claims 1-5, 7, 11-14, 16-20, 23-25 and 27 are pending. The Examiner further states that claims 14, 16-20, 23 and 27 were previously withdrawn but are examined in the January 7, 2009 Office Action. The Office Action Summary states that claims 14, 16-20, 23 and 27 are rejected; however, the Examiner has not set forth with particularity any objection or rejection of these claims.

Applicants respectfully request clarification regarding the Examiner's consideration of claims 14, 16-20, 23 and 27 in the next Office Communication.

### **II. The Rejection of Claim 5 under 35 U.S.C. 112 (Second Paragraph)**

Claim 5 stands rejected under 35 U.S.C. 112, second paragraph as allegedly indefinite in reciting the phrase "comprising a substitution... of one or more amino acid residues." This rejection is respectfully traversed.

Solely to expedite prosecution, Applicants have amended claim 5 to recite that the variant comprises a substitution, deletion and/or insertion of one or more amino acid residues of a protease having the amino acid sequence shown as amino acids -25 to 226 of SEQ ID NO:2. Applicants respectfully submit that the Examiner's rejection is thereby obviated.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112, second paragraph. Applicants respectfully request reconsideration and withdrawal of the rejection.

### **III. The Rejection of Claims 1-2, 5, 7, 11-13 and 24-25 under 35 U.S.C. 112 (Enablement)**

Claims 1-2, 5, 7, 11-13 and 24-25 stand rejected under 35 U.S.C. 112, first paragraph as allegedly lacking enablement. The Examiner contends that by use of the "comprising" language,

the claims encompass proteases wherein the activity is not derived from the sequence homologous to SEQ ID NO: 2. This rejection is respectfully traversed.

Solely to expedite prosecution, Applicants have amended the claims to recite an isolated protease comprising an amino acid sequence which a) has at least 90% identity with the amino acid sequence shown as amino acids 1 to 226 of SEQ ID NO: 2 and b) protease activity. Applicants respectfully submit that the Examiner's rejection is thereby obviated.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112, first paragraph (enablement). Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **IV. The Rejection of Claims 1-2, 5, 7, 11-13 and 24-25 under 35 U.S.C. 112 (Written Description)**

Claims 1-2, 5, 7, 11-13 and 24-25 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking written description. The Examiner contends that by use of the "comprising" language, the claims encompass proteases wherein the activity is not derived from the sequence homologous to SEQ ID NO: 2. This rejection is respectfully traversed.

Solely to expedite prosecution, Applicants have amended the claims to recite an isolated protease comprising an amino acid sequence which a) has at least 90% identity with the amino acid sequence shown as amino acids 1 to 226 of SEQ ID NO: 2 and b) protease activity. Applicants respectfully submit that the Examiner's rejection is thereby obviated.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112, first paragraph (written description). Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **V. The Rejection of Claims 1-5, 7, 10-13 and 24 under 35 U.S.C. 102**

Claims 1-5, 7, 10-13 and 24 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by Isono et al., USPN 3,655,570 (hereinafter "Isono") as evidenced by Isono and Esaki et al., Arch. Microbiol., 161:110-115 (1994) (hereinafter "Esaki"). The Examiner has maintained the rejection for the reasons set forth in the April 7, 2008 Office Action; namely, that the Examiner "believes" the protease of Isono is the same as that set forth in SEQ ID NO:2. This rejection is respectfully traversed.

Anticipation is a question of fact, and an anticipatory reference must disclose each and every limitation of the claimed invention, either expressly or inherently. The fact that a certain

result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1991) (citations omitted). “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). See also MPEP 2112 IV.

The Examiner states that Isono teaches an alkaline protease isolated from *F. solani* that shows activity in a detergent composition. The Examiner contends that Isono’s *F. solani* alkalkine protease is “more likely than not” to have thermostability because an alkaline protease isolated from an entirely separate *Fusarium* species has thermostability, and because an entirely separate enzyme (an aminotransferase, as demonstrated by Esaki) isolated from *F. solani* has thermostability. On this basis, the Examiner concludes that the skilled artisan would believe that it is “more likely than not” that Isono’s protease from *F. solani* is the same as the protease of SEQ ID NO:2.

Applicants respectfully submit that the Examiner has not met the required burden of providing a rationale or evidence tending to show the alleged inherency of the pending claims. Importantly, the Examiner has not provided sufficient basis to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of Isono, alone or as evidenced by Esaki.

Applicants claims are directed to an isolated protease comprising an amino acid sequence which a) has at least 90% identity with the amino acid sequence shown as amino acids 1 to 226 of SEQ ID NO: 2 and b) has protease activity.

In contrast, Isono purports to provide a strain of alkali-protease producing microorganisms belonging to the genus *Fusarium* or the genus *Gibberella*, and provides that *F. solani* is one of some typical microorganisms producing the alkali protease. See Isono, col. 1, lines 30-44. Table 5 of Isono purports to provide protease activity of a solution obtained from *F. solani*. See Isono, Example 6. Isono does not provide any working example providing the sequence of a protease, obtained from *F. solani* or otherwise.

Esaki describes another enzyme, alpha-dialkylamino acid aminotransferase, found in various fungi, including *F. solani*. See Esaki, Abstract.

Nowhere has the Examiner identified – in Isono, Esaki, or otherwise – any teaching of an isolated protease comprising an amino acid sequence which a) has at least 90% identity with the amino acid sequence shown as amino acids 1 to 226 of SEQ ID NO: 2 and b) has protease activity. Thus, the Examiner has not met the Office's initial burden of establishing a *prima facie* basis to deny the novelty of Applicants' pending claims. The Examiner's assertions do not justify a determination that Isono, alone or as evidenced by Esaki, discloses Applicants' claimed isolated protease.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102(b). Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **VI. The Rejection of Claims 24-25 under 35 U.S.C. 103**

Claims 24-25 stand rejected under 35 U.S.C. 103 as allegedly being unpatentable over Isono in view of Okuda, US 2004/0002432 (hereinafter "Okuda"). The Examiner again references the rejections of the April 7, 2008 Office Action, stating that Okuda teaches a detergent composition comprising an alkaline protease and optionally further components, and alleges that it would have been obvious to produce a detergent composition comprising an alkaline protease of Isono and optionally further comprising other components. This rejection is respectfully traversed.

The teachings of Isono are discussed above. As previously set forth, nowhere does Isono teach or suggest an isolated protease comprising an amino acid sequence which a) has at least 90% identity with the amino acid sequence shown as amino acids 1 to 226 of SEQ ID NO: 2 and b) has protease activity.

Nor does Okuda cure this defect. Okuda is directed to an alkaline protease having particular amino acid residues at certain positions. See Okuda, Abstract. Again, nowhere does Okuda describe an isolated protease comprising an amino acid sequence which a) has at least 90% identity with the amino acid sequence shown as amino acids 1 to 226 of SEQ ID NO: 2 and b) has protease activity.

Accordingly, neither Isono or Okuda, either alone or in combination, render Applicants' claims obvious.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

## **VII. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Should any fees be due, please charge deposit account no. 50-1701 of Novozymes North America Inc.

Respectfully submitted,

Date: April 2, 2009

/Kristin McNamara, Reg. # 47692/

Kristin J. McNamara, Reg. No. 47,692

Novozymes North America, Inc.

500 Fifth Avenue, Suite 1600

New York, NY 10110

(212) 840-0097